UNITED STATES DISTRICT COURT DISTRICT OF SOUTH CAROLINA SPARTANBURG DIVISION

State of South Carolina ex rel. Alan Wilson, in his capacity as Attorney General of the State of South Carolina,) C/A No.: 7:11-cv-01475-GRA))
Plaintiff,)
V.) ORDER) (Written Opinion)
GlaxoSmithKline, LLC, formerly SmithKline Beecham Corp., d/b/a GlaxoSmithKline,))))
Defendant.)))

This matter comes before the Court on the State of South Carolina's (the "State") Motion to Remand. For the reasons set forth below, the Court grants the State's Motion.

Background

On May 17, 2011, Attorney General Alan Wilson, acting on behalf of the State, filed this action against GlaxoSmithKline, LLC ("GSK") in the Court of Common Pleas for the Seventh Judicial Circuit, Spartanburg County, South Carolina. The case pertains to GSK's marketing, sale, and promotion of a diabetes medication commonly known as Avandia. Under the State's Medicaid and State Health Plan ("SHP") programs, the State reimbursed pharmacies, doctors, and hospitals for Avandia prescriptions written for and dispensed to participants in the programs. In

its complaint, the State alleges GSK misrepresented the safety and effectiveness of Avandia, thereby causing doctors to prescribe it, rather than safer or less expensive drugs, to patients who use South Carolina's Medicaid and SHP programs. Based on these allegations, the State asserts the following causes of action: submission of false and fraudulent claims, in violation of the South Carolina Medicaid Fraud Act, S.C. Code Ann. § 43-7-60 ("SCMFA"); violation of the South Carolina Unfair Trade Practices Act, S.C. Code Ann. §§ 39-5-10 *et. seq.*; strict products liability; negligence; breach of warranty; fraudulent and negligent misrepresentation; and unjust enrichment.

On June 16, 2011, GSK removed this action to federal court pursuant to 28 U.S.C. §§ 1331, 1441, and 1446, alleging the State's claims raise important and substantial questions requiring the interpretation of the federal Food, Drug, and Cosmetic Act ("FDCA"), Food and Drug Administration ("FDA") regulations, and federal Medicaid law. The State filed its Motion to Remand on June 27, 2011.

Meanwhile, on June 17, 2011, GSK filed a Motion to Stay all proceedings in the case pending transfer by the Judicial Panel on Multidistrict Litigation ("JPML") to the Avandia MDL pending in the Eastern District of Pennsylvania. On June 20, 2011, the JMPL entered a conditional transfer order, conditionally transferring this action to the Eastern District of Pennsylvania as part of the Avandia MDL.¹ On June

The pendency of the conditional transfer order does not deprive this Court of jurisdiction to rule on the Motion to Remand. *See* JPML R. 2.1(d).

28, 2011, this Court granted in part GSK's Motion, staying activity in the case on all issues except the pending Motion to Remand.

Standard of Review

The defendant bears the burden of establishing the existence of removal jurisdiction. *Mulachey v. Columbia Organic Chems. Co.*, 29 F.3d 148, 151 (4th Cir. 1994). Because removal jurisdiction raises significant federalism concerns, a district court must strictly construe removal jurisdiction. *Id.* (citing *Shamrock Oil & Gas Corp. v. Sheets*, 313 U.S. 100 (1941)). If federal jurisdiction is in doubt, remand to state court is necessary. *Id.* Where, as here, the defendant bases subject matter jurisdiction on the presence of a federal question, the court must evaluate jurisdiction by reference to the plaintiff's well-pleaded complaint. *Merrell Dow Pharms., Inc. v. Thompson*, 478 U.S. 804, 808 (1986). A defense that raises a federal question is inadequate to confer federal question jurisdiction. *Id.*

Discussion

"In order for removal jurisdiction to exist, a federal court must have original jurisdiction." *Gressette v. Sunset Grille, Inc.*, 447 F. Supp. 2d 533, 535 (D.S.C. 2006). Thus, in considering whether to remand this action to state court, the ultimate question this Court must answer is whether it possesses subject matter jurisdiction over this case.

GSK argues that even though the State's complaint asserts state-law causes of action, this Court possesses federal question jurisdiction under 28 U.S.C. § 1331

because the State's claims necessarily raise substantial questions of federal law. When a complaint alleges only state-law causes of action, a federal court may exercise jurisdiction under § 1331 only if a "state-law claim necessarily raises a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state responsibilities." *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314 (2005). GSK relies on *Grable* as the basis for the Court's jurisdiction.

GSK first argues the State's cause of action for violation of the SCMFA raises substantial and disputed issues of federal Medicaid law because the State's statutory fraud cause of action "hinge[s] on" the question of whether the federal Medicaid statute permits the State to refuse to pay for prescriptions of Avandia, an FDA-approved drug. In three previous decisions from this District involving similar facts, the Honorable Henry F. Floyd and the Honorable Henry M. Herlong rejected this argument. State of South Carolina ex Rel. McMaster v. Astra Zeneca Pharmaceuticals LP, No. 7:09-cv-387-HFF, 2009 WL 1227848 (D.S.C. May 5, 2009) (Astra Zeneca), State of South Carolina ex rel. Henry McMaster v. Eli Lilly & Co., Inc., No. 7:07-cv-1875-HMH, 2007 WL 2261693 (D.S.C. Aug. 3, 2007) (Eli Lilly), and State of South Carolina ex rel. Henry McMaster v. Janssen Pharmaceutica Inc., No. 7:07-cv-1452-HMH, 2007 WL 2022173 (D.S.C. July 10, 2007) (Janssen), involved cases in which the State asserted SCMFA causes of action

against pharmaceutical companies that manufactured antipsychotic drugs. In Janssen, Judge Herlong considered the argument GSK asserts here and concluded that

no substantial federal question exists to support a finding of jurisdiction. The Defendants' liability will solely depend upon their respective breach of duties as defined and created by state law. "Simply put, it is not the act of causing the submission of a claim for a non-medically accepted indication that creates liability under the state law causes of action, but rather the act of causing the submission of a false or fraudulent claim." Pennsylvania v. Eli Lilly & Co., Inc., [511 F. Supp. 2d 576, 582 (E.D. Pa. 2007).] For example, if the State proves at trial that the Defendants violated the Federal Medicaid Act, it would not necessarily follow that the Defendants committed Medicaid fraud as defined in S.C. Code Ann. §§ 43-7-60.

Janssen, 2007 WL 2022173, at *2. Judge Herlong reiterated this conclusion in Eli Lilly, 2007 WL 2261693, at *2, and, in Astra Zeneca, Judge Floyd quoted it, 2007 WL 1227848, at *4.

This Court agrees with Judge Herlong's analysis, which is consistent with the conclusions of a number of other district courts that have remanded similar cases. See Astra Zeneca, 2009 WL 1227848, at *5 (collecting cases). Furthermore, it is consistent with Grable itself. In Grable, a quiet title action, the only disputed issue was the meaning of a section of the Internal Revenue Code, as title to the land turned solely on the meaning of that section. 545 U.S. at 315. Here, though, the State does not dispute its general obligation under federal Medicaid law to pay for covered prescription drugs. Instead, it alleges GSK violated the SCMFA by misrepresenting the efficacy and value of Avandia. As one district judge put it,

"claiming that Defendants wrongfully triggered the State's obligation to pay [for a particular drug] is completely different than claiming that the State should not have such an obligation as a matter of law, despite the requirements of the federal Medicaid statute." *New Mexico v. Ortho-McNeil-Janssen Pharms., Inc.*, No. CIV 08-0779, slip op., at 4 (D.N.M. Jan. 26, 2009).

Attempting to distinguish this case from *Astra Zeneca*, *Eli Lilly*, and *Janssen*, GSK argues that because the State is suing for all Avandia prescriptions written for South Carolina Medicaid recipients, it is effectively challenging its federal-law obligation to pay, and because federal Medicaid law delineates the exclusive means by which a state can refuse to pay, the State's SCMFA claim therefore necessarily raises a substantial and disputed federal issue. This Court is not persuaded. Liability under the SCMFA arises when a person "make[s] or causes to be made a false claim, statement, or representation of material fact." S.C. Code Ann. § 43-7-60(B). The SCMFA liability does not require that a false statement induce the State to pay a claim. Accordingly, it is not necessary that the State show that but for the falsity of the statement, it would not have been obligated, under federal Medicaid law, to pay the claim. GSK has failed to prove that the State's SCMFA claim necessarily raises a substantial and disputed issue of federal Medicaid law.²

Other than generally stating in the Notice of Removal that the State's claims "hinge on" the interpretation of federal Medicaid law, GSK advances no argument as to how any of the State's other causes of action necessarily raise substantial issues of federal law. Thus, with regard to the federal Medicaid law argument, the Court finds that GSK

State's claims require interpretation of the FDCA and FDA regulations pertaining to drug labeling and marketing. *Merrell Dow* forecloses that argument. In *Merrell Dow*, the defendant drug company argued that a substantial federal issue existed because the plaintiff's state tort claim rested in part on the allegation that the defendant had violated the FDCA and was thus presumptively negligent under Ohio law. 478 U.S. at 805–06. The Supreme Court disagreed, concluding that the assertion of an FDCA violation as an element of a state tort claim is not a sufficiently substantial issue to confer federal question jurisdiction. *See id.* at 817.

GSK also asserts that because the State alleges GSK violated the FDCA, the

Moreover, GSK has already presented this argument to the Honorable Cynthia M. Rufe, who is presiding over the Avandia MDL. *See In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 624 F. Supp. 2d 396, 400–01 (E.D. Pa. 2009) ("*In re Avandia*"). Citing *Merrell Dow* and *Grable*, Judge Rufe rejected GSK's argument and concluded there was no federal question jurisdiction in any of the seventeen cases discussed in her opinion. *Id.* at 416.

GSK attempts to distinguish Judge Rufe's opinion by noting that the cases she remanded were individual personal injury actions grounded in common law failure-to-warn claims. Unlike those actions, GSK argues, the State claims in this case "that Avandia should not be reimbursable, in part because GSK has allegedly

has failed to meet its burden as to those remaining state law claims. *See Astra Zeneca*, 2209 WL 1227848, at *4 n.4.

withheld information from the FDA and violated FDA regulations." The Court is again unpersuaded. First, the majority of the State's claims here are common law claims, including failure to warn. Second, GSK's characterization of the State's complaint misses the State's point. The State's allegations of violations of FDCA and FDA regulations simply illustrate the State's perception of the alleged falsity of GSK's representations regarding Avandia. In other words, the State is not claiming that because GSK violated the FDCA and FDA regulations, its representations regarding Avandia are therefore false; the State is claiming that GSK made false representations that, incidentally, ran afoul of FDA regulations and the FDCA. Thus, GSK has not shown that any of the State's causes of action necessarily raises a substantial and disputed issue of federal law.

GSK's failure to satisfy the first prong of *Grable* warrants remand for lack of subject matter jurisdiction. GSK also fails to prove that exercising federal question jurisdiction over this case would comport with congressional judgment on balances of state and federal power.

In *Grable*, the Supreme Court explained why, in its earlier decision in *Merrell Dow*, it found there was no federal question jurisdiction:

[a] general rule of exercising federal jurisdiction over state claims resting on federal . . . statutory violations would . . . have heralded a potentially enormous shift of traditionally state cases into federal courts. Expressing concern over the "increased volume of federal litigation," and noting the importance of adhering to "legislative intent," *Merrell Dow* thought it improbable that the Congress, having made no provision for a federal cause of action, would have meant to welcome [in federal courts] any state-law tort case implicating federal

law "solely because the violation of the federal statute is said to [create] a rebuttable presumption [of negligence] . . . under state law." In this situation, no welcome mat meant keep out.

Id. at 319 (internal citations omitted). Basically, "if the federal labeling standard without a federal cause of action could get a state claim into federal court, so could any other federal standard without a federal cause of action. And that would have meant a tremendous number of cases." Id. at 318. Merrell Dow, which dealt with a negligence claim implicating the FDCA, therefore undercuts GSK's argument that Congress, in passing the FDCA, intended that statute or its implementing regulations to serve as a basis for federal question jurisdiction. Judge Rufe has concluded as much, see In re Avandia, 624 F. Supp. 2d at 416, and this Court agrees.

As for the federal Medicaid statute, Judge Floyd and Judge Herlong have concluded Congress did not intend that federal courts have jurisdiction over the type of case presented here. In *Janssen*, Judge Herlong reasoned as follows:

In general, "the absence of a federal private right of action [is] evidence relevant to, but not dispositive of, the sensitive judgments about congressional intent that § 1331 requires." [Grable, 545 U.S.] at 318 (internal quotation marks omitted). However, in contrast to the facts in *Grable*, a finding of federal jurisdiction over any state cause of action implicating provisions of the Federal Medicaid Act and its accompanying regulations could "attract[] a horde of original filings and removal cases raising other state claims with embedded federal issues." *Id.* Under these circumstances, the fact that Congress provided no private right of action in the Federal Medicaid Act presents compelling evidence that a finding of federal jurisdiction in the instant case would not be "consistent with congressional judgment about the sound division of labor between state and federal courts." *Id.* at 313.

Further supporting that finding is the fact that the Federal Medicaid Act requires states to seek recovery of Medicaid funds from liable third parties. 42 U.S.C. § 1396a(a)(25) (West Supp. 2007); see New York v. Lutheran Ctr. for the Aging, Inc., 957 F. Supp. 393, 403 (E.D.N.Y. 1997) ("Where a federal statute such as Medicaid requires a state to enforce liability against a third party but does not provide the ground for that liability, nor require establishment of a ground for liability, federal question jurisdiction will not lie."). Therefore, a finding of federal jurisdiction in the instant case would not be "consistent with congressional judgment about the sound division of labor between state and federal courts." *Grable*, 545 U.S. at 313.

Janssen, 2007 WL 2022172, at *2-3. This Court agrees with Judge Herlong's reasoning.

GSK argues federal courts have an interest in the uniform interpretation of federal statutes and regulations. *Merrell Dow* rejected that argument. In addition to disagreeing with the defendant's emphasis on the federal interest in having uniform interpretations of the FDCA, the *Merrell Dow* Court noted that "even if there is no original district court jurisdiction for these kinds of action, [the Supreme] Court retains power to review the decision of a federal issue in a state cause of action." 478 U.S. at 816. Echoing *Merrell Dow*, Judge Rufe notes that "[a]ny abiding federalism concerns may be allayed by the fact that any such determination [by a state court] would be subject to review by the United States Supreme Court." *In re Avandia*, 624 F. Supp. 2d at 416.

Finally, GSK argues that because an MDL is pending, judicial efficiency and economy will be served by keeping the case in federal court and allowing it to be transferred to the MDL. However, when a sovereign State brings a claim,

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"considerations of comity make [the Court] reluctant to snatch cases which a State

has brought from the courts of that State, unless some clear rule demands it."

Franchise Tax Bd. v. Constr. Laborers Vacation Trust, 463 U.S. 1, 21 n.22 (1983)

(emphasis added). GSK's efficiency argument does not illustrate a clear rule

demanding removal.

In sum, GSK has not shown that any cause of action in the State's complaint

necessarily raises a substantial and disputed issue of federal law and that exercising

federal question jurisdiction over this action would comport with congressional

intent. With federal subject matter jurisdiction therefore in doubt, this Court is

obligated to remand the action to state court.

IT IS THEREFORE ORDERED THAT Defendant's Motion to Remand (ECF No.

17) be GRANTED. This case is hereby REMANDED to the Court of Common Pleas

for Spartanburg County, South Carolina.

The Clerk of Court is hereby directed to mail a certified copy of this Order to

the Clerk of Court of Common Pleas, Spartanburg County, South Carolina.

IT IS SO ORDERED.

G. Ross Anderson, Jr.

Senior United States District Judge

July <u>22</u>, 2011 Anderson, South Carolina